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10/081,393	02/20/2002	Larry E. Morrison	01886-071001/ V0079	1580

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EXAMINER	
CHAKRABARTI, ARUN K	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 07/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/081,393	Applicant(s) Morrison
	Examiner Arun Chakrabarti	Art Unit 1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 12, 2003* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above, claim(s) *8-20* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-7* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *0303*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action*

DETAILED ACTION

Election/Restriction

1. Applicant's election of Group I, corresponding to claims 1-7, with traverse submitted on March 2, 2003, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicant's election of species of element (a) of claim 1, submitted on May 22, 2003, is also hereby acknowledged.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Ried et al. (U.S. Patent 5,919,624) (July 6, 1999).

Ried et al. teaches a set of chromosomal probes comprising the combination of two probes 5p and 3q (Column 7, lines 18-30, and Table 1, and Claims 1 and 4).

Ried et al. teaches the set of chromosomal probes, wherein different detection moieties comprising fluorescent labels are attached to the two probes (Column 4, lines 26-65, and Examples, Column 7, line 64 to Column 8, line 24).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claim 6 is rejected under 35 U.S.C.103(a) over Halling et al. (U.S. Patent 6,376,188 B1) (April 23, 2002) in view of McGill et al. (U.S. Patent 5,658,730) (August 19, 1997) further in view of Bastian et al. (U.S. Patent 6,465,180 B1) (October 15, 2002).

Halling et al. teaches a set of three chromosomal probes comprising the combination of 9p21 locus specific probe and probe of chromosome 8 (Column 2, lines 50-59, and Column 5, lines 29-40, and Claims 1-13).

Halling et al. does not teach specifically chromosomal probe 8q24.

McGill et al. teaches specifically chromosomal probe 8q24 (Abstract, and Claims 1-24, and Figures 1-3).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute a method, wherein one of the probes is 8q24 locus specific probe of McGill et al. into the set of three chromosomal probes of Halling et al., since McGill et al. states, "Genetic probes and methods useful in monitoring the progression and diagnosis of prostate cancer are described (Abstract, lines 2-4). " By employing scientific reasoning, an ordinary artisan would have combined and substituted a method, wherein one of the probes is 8q24 locus specific probe of McGill et al. into the set of three chromosomal probes of Halling et al. in order to improve the analysis of a plurality of target nucleic acid involved in different diseases. An ordinary practitioner would have been motivated to combine and substitute a method, wherein one of the probes is 8q24 locus specific probe of McGill et al. into the set of three chromosomal probes of Halling et al., in order to achieve the express advantages, as noted by McGill et al., of a novel invention that provides both genetic probes and methods useful in monitoring the progression and diagnosis of prostate cancer.

Halling et al. in view of McGill et al. do not teach a 5p15 locus specific probe.

Bastian et al. teach a 5p15 locus specific probe (Column 17, lines 14-17, and Claim 1).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute a method, wherein one of the probes is 5p15 locus specific probe of Bastian et al. into the set of three chromosomal probes of Halling et al., in view of McGill et al. since Bastian et al. states, "The identification of useful means by which morphologically normal premalignant cells that have the capacity to form melanomas can be identified. The present invention addresses these and other needs (Column 1, lines 50-53). " By employing scientific reasoning, an ordinary artisan would have combined and substituted a method, wherein one of the probes is 5p15 locus specific probe of Bastian et al. into the set of three chromosomal probes of Halling et al., in view of McGill et al. in order to improve the analysis of a plurality of target nucleic acid involved in different diseases. An ordinary practitioner would have been motivated to combine and substitute a method, wherein one of the probes is 5p15 locus specific probe of Bastian et al. into the set of three chromosomal probes of Halling et al., in order to achieve the express advantages, as noted by Bastian et al., of a novel invention that addresses the identification of useful means by which morphologically normal premalignant cells that have the capacity to form melanomas can be identified.

6. Claim 7 is rejected under 35 U.S.C.103(a) over Bastian et al. (U.S. Patent 6,465,180 B1) (October 15, 2002) in view of McGill et al. (U.S. Patent 5,658,730) (August 19, 1997) further in view of Vogelstein et al. (U.S. Patent 6,127,126) (October 3, 2000) further in view of Nuell et al. (U.S. Patent 5,658,792) (August 19, 1997).

Bastian et al. teaches a set of chromosomal probes comprising the combination of 5p15 locus specific probe (Column 17, lines 14-17, and Claim 1).

Bastian et al. does not teach specifically chromosomal probe 8q24.

McGill et al. teaches specifically chromosomal probe 8q24 (Abstract, and Claims 1-24, and Figures 1-3).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute a method, wherein one of the probes is 8q24 locus specific probe of McGill et al. into the set of chromosomal probes of Bastian et al., since McGill et al. states, "Genetic probes and methods useful in monitoring the progression and diagnosis of prostate cancer are described (Abstract, lines 2-4). " By employing scientific reasoning, an ordinary artisan would have combined and substituted a method, wherein one of the probes is 8q24 locus specific probe of McGill et al. into the set of chromosomal probes of Bastian et al. in order to improve the analysis of a plurality of target nucleic acid involved in different diseases. An ordinary practitioner would have been motivated to combine and substitute a method, wherein one of the probes is 8q24 locus specific probe of McGill et al. into the set of chromosomal probes of Bastian et al., in order to achieve the express advantages, as noted by McGill et al., of a novel invention that provides both genetic probes and methods useful in monitoring the progression and diagnosis of prostate cancer.

Bastian et al. in view of McGill et al. do not teach a 7p12 locus specific probe.

Vogelstein et al. teach a 7p12 locus specific probe (Column 16, lines 55-65).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute a method, wherein one of the probes is 7p12 locus specific probe of Vogelstein et al. into the set of chromosomal probes of Bastian et al. in view of McGill et al. since Vogelstein et al. states, "The invention provides an important step forward in the diagnosis and treatment of tumors associated with altered EGFR genes (Column 6, lines 39-41). " By employing scientific reasoning, an ordinary artisan would have combined and substituted a method, wherein one of the probes is 7p12 locus specific probe of Vogelstein et al. into the set of chromosomal probes of Bastian et al. in view of McGill et al. in order to improve the analysis of a plurality of target nucleic acid involved in different diseases. An ordinary practitioner would have been motivated to combine and substitute a method, wherein one of the probes is 7p12 locus specific probe of Vogelstein et al. into the set of chromosomal probes of Bastian et al. in view of McGill et al. in order to achieve the express advantages, as noted by Vogelstein et al., of a novel invention that provides an important step forward in the diagnosis and treatment of tumors associated with altered EGFR genes.

Bastian et al. in view of McGill et al. further in view of Vogelstein et al. do not teach a 17q21 locus specific probe.

Nuell et al. teach a 17q21 locus specific probe (Column 10, lines 24-37, and Claim 18).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute a method, wherein one of the probes is 17q21 locus specific probe of Nuell et al. into the set of chromosomal probes of Bastian et al. in view of

McGill et al. further in view of Vogelstein et al. since Nuell et al. states, "The chromosomal localization of prohibitin to the region 17q21-22 implies that it may be used as a restriction fragment length polymorphism probe for diseases resulting from deletion or rearrangement of this and nearby regions of the chromosome. Such rearrangements have been implicated in the etiology of acute myelogenous leukemia (Column 10, lines 24-31). " By employing scientific reasoning, an ordinary artisan would have combined and substituted a method, wherein one of the probes is 17q21 locus specific probe of Nuell et al. into the set of chromosomal probes of Bastian et al. in view of McGill et al. further in view of Vogelstein et al. in order to improve the analysis of a plurality of target nucleic acid involved in different diseases. An ordinary practitioner would have been motivated to combine and substitute a method, wherein one of the probes is 7p12 locus specific probe of Nuell et al. into the set of chromosomal probes of Bastian et al. in view of McGill et al. further in view of Vogelstein et al. in order to achieve the express advantages, as noted by Nuell et al., of a novel invention that may be used as a restriction fragment length polymorphism probe for diseases resulting from deletion or rearrangement of the chromosome, which have been implicated in the etiology of acute myelogenous leukemia.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph. D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119. The fax phone number for this Group is (703)746-4979.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237.

Arun Chakrabarti,

Patent Examiner,

June 11, 2003